

**REMARKS**

Reconsideration and withdrawal of the restriction requirement and election of species are respectfully requested in view of the remarks herein.

**I. STATUS OF THE CLAIMS AND FORMAL MATTERS**

Claims 1-22 are currently pending. Claims 1-21 have been amended, and claims 23-29 have been cancelled, without prejudice, without admission, without surrender of subject matter, and without any intention of creating any estoppel as to equivalents.

No new matter is added.

It is respectfully submitted that the claims herewith and as previously pending are and were patentably distinct from the references cited by the Examiner, and that these claims are and were in full compliance with the requirements of 35 U.S.C. § 112. The amendments to the claims herein are not made for the purpose of patentability within the meaning of 35 U.S.C. §§ 101, 102, 103 or 112; but rather the amendments are made simply for clarification and to round out the scope of protection to which Applicants are entitled.

**II. THE OBJECTION TO THE DRAWINGS IS OVERCOME**

The Office Action questioned whether color drawings were including in the filing of the application, and reminded Applicants that a petition under 37 CFR 1.84(a)(2) is necessary for color drawings to be accepted.

Applicants respectfully submit that any deficiencies in the drawings, will be corrected in due course, and the Examiner is thanked for the courteous reminder.

**III. PRIORITY DOCUMENTS WILL BE PROVIDED IN DUE COURSE**

The Office Action stated that a certified copy of the foreign priority document had not yet been received. Applicants are obtaining certified copies and verified translations of the priority documents as necessary, and will provide the documents in due course. However, Applicants note that the present application also claims priority to US Provisional Application 60/281,923, which provides a priority date of April 6, 2001, the same date as the earliest French priority application.

#### **IV. THE DOUBLE PATENTING REJECTIONS ARE OVERCOME**

Claims 1-29 were provisionally rejected under 35 U.S.C. §101 as allegedly claiming the same invention as that of claims 1-29 of copending Application No. 10/679,520. Claims 1-29 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as allegedly being unpatentable over claims 21-27 of copending Application Serial No. 10/679,520. The rejections are respectfully traversed.

The present application now relates to a vaccine composition and a method of providing a protective immune response. In contrast, USSN 10/679,520 relates to an immunogenic composition and method of providing an immune response. Applicants respectfully believe that the double patenting rejections should be reconsidered and withdrawn in view of the amendments herein.

In any event, each of the double patenting rejections made in the Office Action were provisional as no claims have yet been found allowable. Applicants respectfully request that the rejections be reconsidered and withdraw, or alternatively, held in abeyance until such time as allowable subject matter is has been determined, at which time the rejections should be revisited to determine whether or not they are applicable.

#### **V. THE REJECTIONS UNDER 35 U.S.C. §112 ARE OVERCOME**

Claims 17-20, 22, 25, 26 and 28 were rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter of the invention. The rejection is respectfully traversed.

- The Office Action further described the rejections as follows:
- Claims 17 and 18 allegedly lacked antecedent basis for the recitation "vaccine composition";
- Claim 19 allegedly lacked antecedent basis for the recitation "the adjuvant";
- Claims 18 and 20 allegedly refer to "the composition according to" a prior claim, but the cited claims are drawn to methods, not compositions;
- Claim 20 allegedly refers to a response against another pathogen, but nothing in the claim or the parent claims to a component from another pathogen; and,
- Claim 25 allegedly lacks antecedent basis for "(a) and (b)".

Applicants respectfully submit that the amendments to the claims herewith have addressed the rejections as described above.

Accordingly, reconsideration and withdrawal of the rejections under 35 U.S.C. §112, second paragraph, is respectfully requested.

**VI. THE ART REJECTIONS ARE OVERCOME**

Claims 1, 16, 17, 18 and 29 were rejected under 35 U.S.C. §102(e) as allegedly being unpatentable under Chang et al. US 2003/0022849. Claims 1, 7, 10-12 and 16 were rejected under 35 U.S.C. §102(e) as allegedly being unpatentable under WO 01/60847. Claims 1-3, 7 and 16 were rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Yamshikov et al. Claims 17 and 18 were rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over WO 01/60847. Claims 10-13 were rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over US 2003/0022849. Claims 1-13, 15-18 and 20 were rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over the combined teaching of Paoletti (a) (US 5,744,141), US 2003/0022849 and Paoletti (b) (US 5,505,941). Claims 21, 22, 27 and 28 were rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over the combined teaching of Paoletti (a) (US 5,744,141), US 2003/0022849 and Paoletti (b) (US 5,505,941) and further in view of Ramshaw. Claims 23-26 were rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Paoletti (a) (US 5,744,141), US 2003/0022849 and Paoletti (b) (US 5,505,941) and further in view of Paoletti (c) US 5,338,683). Claims 14 and 19 were rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Paoletti (a) (US 5,744,141), US 2003/0022849 and Paoletti (b) (US 5,505,941) and further in view of Audonnet et al. (WO 99/44633). Claims 1-11, 16-18 and 22 were rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Paoletti (d) (Proc. Natl. Acad. Sci. USA 1996) in view of both Goverdhan and Ostlund, as evidenced by Paoletti (e) (US 5,756,103). Claims 1-12, 16-18, 22 and 29 were rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Paoletti (d) (Proc. Natl. Acad. Sci. USA 1996) in view of both Goverdhan and Ostlund, and further in view of both Stocks and Chang. Claims 1-11, 13, 14, 16-20 and 22 were rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Paoletti (d) (Proc. Natl. Acad. Sci. USA 1996) in view of both Goverdhan and Ostlund, and in further view of Mumford. Claims 1-11, 15-18 and 22 were rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Paoletti (d) (Proc. Natl.

Acad. Sci. USA 1996) in view of both Goverdhan and Ostlund, in further view of Varga. And, claims 1-11, 16-18, 21 and 22 were rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Paoletti (d) (Proc. Natl. Acad. Sci. USA 1996) in view of both Goverdhan and Ostlund, and in further view of Ruitengerg. The rejections are respectfully traversed and will be addressed collectively.

It is respectfully pointed out that a two-prong inquiry must be satisfied in order for a Section 102 rejection to stand. First, the prior art reference must contain all of the elements of the claimed invention. *See Lewmar Marine Inc. v. Barient Inc.*, 3 U.S.P.Q.2d 1766 (Fed. Cir. 1987). Second, the prior art must contain an enabling disclosure. *See Chester v. Miller*, 15 U.S.P.Q.2d 1333, 1336 (Fed. Cir. 1990). A reference contains an enabling disclosure if a person of ordinary skill in the art could have combined the description of the invention in the prior art reference with his own knowledge of the art to have placed himself in possession of the invention. *See In re Donohue*, 226, U.S.P.Q. 619, 621 (Fed. Cir. 1985).

Further, the Examiner is respectfully reminded that for a Section 103 rejection to be proper, there must be some prior art teaching which would have provided the necessary incentive or motivation for modifying the reference teachings to arrive at the claimed invention. *In re Laskowski*, 12 U.S.P.Q. 2d 1397, 1399 (Fed. Cir. 1989); *In re Obukowitz*, 27 U.S.P.Q. 2d 1063 (BPAI 1993). Further, the Examiner is respectfully reminded that “obvious to try” is not the standard under 35 U.S.C. §103. *In re Fine*, 5 U.S.P.Q. 2d 1596, 1599 (Fed. Cir. 1988). And, as stated by the Court in *In re Fritch*, 23 U.S.P.Q. 2d 1780, 1783-1784 (Fed. Cir. 1992): “The mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggests the desirability of the modification.”

And, for the Section 103 rejection to be proper, **both the suggestion of the claimed invention and the expectation of success must be founded in the prior art, and not Applicants’ disclosure.** *In re Dow*, 5 U.S.P.Q.2d 1529, 1531 (Fed. Cir. 1988). Furthermore, the Examiner is also respectfully reminded that MPEP 2143.01 mandates that for a Section 103 rejection, there must be some suggestion or motivation to modify reference teachings, and, that MPEP 2143.02 further mandates that for a section 103 rejection, there must be a reasonable expectation of success.

Applicants respectfully submit that none of the references relied on in the Office Action provide any teaching or suggestion of the present invention, either individually or in any

combination. Furthermore, none of the cited references provide any motivation to combine or any expectation of success.

Initially, Applicants note that claims 23-29 have been cancelled without prejudice herein, such that the rejections of these claims are now moot, and will not be further discussed herein. Accordingly, reconsideration and withdrawal of the rejections of these claims is respectfully requested.

The present invention relates in one aspect to a vaccine composition to induce a protective immune response against West Nile virus (WNV) in an animal susceptible to WNV comprising a vector comprising a recombinant virus or DNA plasmid that encodes and expresses *in vivo* in the animal WNV E; WNV prM and E; WNV M and E; WNV prM, WNV M and E, WNV polyprotein prM-E, WNV polyprotein M-E, or WNV polyprotein prM-M-E.

As to the rejection over Chang (US 2003/0033849), Applicants note that Chang was filed April 4, 2001. In contrast, the present application claims priority to USSN 60/281,923 filed April 6, 2001. Applicants believe that a date of invention of at least April 4, 2001 can be established, and will provide such information in a subsequent document.

Applicants also note that Kinney (WO 01/60847) was filed August 23, 2001, which date is after that of the priority date of the present application through a claim of priority to USSN 60/281,923 filed April 6, 2001. Accordingly, Applicants respectfully submit that Kinney is not available as a reference under 35 U.S.C. §102 and the rejection must therefore be withdrawn.

Turning to Yamshikov, the Office Action states that the reference "does not teach the intended use recited in the claim" but as "the claims are drawn to a product, not a method of use, [the] reference meets each and every definite limitation of the claimed product." Office Action at 5. Applicants respectfully disagree. As amended herein, the application now relates to a vaccine composition. The phrase "vaccine composition" inherently provides information relating to the characteristics of the composition - namely that a protective immune response is conferred by administration of the vaccine composition. Applicants respectfully submit that such a characteristic is an inherent limitation of the claim, such that the lack of teaching in Yamshikov as to a composition which provides a protective immune response indicates that the reference necessarily fails to teach each and every limitation of the claims. Accordingly, the reference must fail under 35 U.S.C. §102.

Similarly, the rejections under 35 U.S.C. §103(a) over WO 01/60847 or US 2003/0033849 must fail as described above.

The Office Action additionally states that the claims are rejected based on the combination of Paoletti (a) (US 5,744,141), US 2003/0022849 and Paoletti (b) (US 5,505,941). As described above, Applicants respectfully submit that information regarding the invention of the present application prior to the filing of US 2003/0022849 will be forthcoming. Furthermore, Applicants respectfully submit that neither Paoletti (a) or (b) teach a vaccine composition to induce a protective immune response against West Nile virus (WNV). Indeed, neither Paoletti (a) or (b) teach the use of West Nile coding sequences in a poxvirus, nor is any teaching, suggestion or motivation found in either of Paoletti (a) or (b) to modify the references to arrive at the present invention. Accordingly, the rejections based on US 2003/0022849 in combination with Paoletti (a) and (b) must also fail.

The additional references Ramshaw, Paoletti (c) (US 5,338,683) and Audonnet are used in combination with the references discussed above to render obvious claims related to a prime/boost administration or those requiring the presence of an adjuvant in the vaccine composition. However, Applicants respectfully submit that as described above, none of these references teach a vaccine composition to induce a protective immune response against West Nile virus (WNV). And, none of Ramshaw, Paoletti (c) or Audonnet correct these deficiencies. Further, Applicants respectfully note that Audonnet is not "another" as to the present application as all of the inventors of the Audonnet reference are also inventors of the present application. Accordingly, none of Ramshaw, Paoletti (c) or Audonnet, either alone or in any combination, anticipate or render obvious the present invention.

The Office Action also states that Paoletti (d) (PNAS 1996) teaches a method of inducing an immunological response against Japanese encephalitis virus (JEV) by administering to a subject an immunogenic composition comprising NYVAC and ALVAC encoding for the polyprotein PrM/M, E of JEV. Moreover, the Office Action states that Goverdhan teaches that immunization with JEV protects against West Nile, and therefore it would be obvious to "develop a vaccine against WNV according to the teachings of Paoletti by replacing the JEV prM/M, E with the WNV prM/M, E, with a reasonable expectation of success." Applicants respectfully disagree.

Paoletti et al. (PNAS 1996) describes the vaccination of pigs using the immunogenic composition comprising NYVAC or ALVAC encoding for the polypeptide PrM/M, E of JEV. Nowhere in Paoletti (d) is the vaccination of horses described. Instead, the Office Action relies on Ostlund for the motivation to develop a West Nile Vaccine for horses.

Initially, it is respectfully submitted that one of skill in the art would have no motivation to combine the cited references as one would not necessarily extrapolate from pigs to horses. Furthermore, one would have no motivation to combine the JEV composition of Paoletti with the WNV vaccine of Goverdhan for at least two reasons. Initially, the WNV vaccine used in Goverdhan comprised formalin-killed WNV. A killed virus vaccine is significantly different from a vectored vaccine as in the present invention, such that there would be no motivation to attempt to prepare a vectored vaccine of WNV based on the killed WNV results. Furthermore, the WNV vaccine utilized in Goverdhan was significantly less protective than was the JEV vaccine. The JEV vaccine resulted in a protective immune response against challenge with WNV. In contrast, the WNV vaccine resulted only in a reduction of the severity of the disease following challenge with JEV (see abstract). Upon reviewing such results, one of skill in the art would have no motivation to select WNV to utilize in the development of a vaccine. To do so would result in a vaccine that was protective only against WNV. In contrast, use of JEV in a vaccine would provide a protective response against both WNV and JEV which would be desired over a vaccine that provided only half of that protection.

Accordingly, the combination of Paoletti (d), Goverdhan and Ostlund does not teach or suggest the present invention, nor is there any motivation to combine or suggestion of success in so doing. As all of the remaining art rejections initially turn on the combination of these three documents, and as none of the remaining cited documents address the deficiencies described above, all of the rejections under §103 fail and must be withdrawn.

Furthermore, Applicants respectfully submit that the present invention provides surprising and unexpected results that enjoy real world success. The Examiner is respectfully invited to review Example 32 of the present application wherein one dose efficacy of a canarypox vectored West Nile Virus vaccine (vCP2017) against a WNV-infected mosquito challenge in horses was described, wherein 1/9 vaccinated horses developed detectable West Nile virus viremia ( 11.1% ), whereas 8/10 control horses (unvaccinated) developed detectable

viremia ( 80% ) post challenge. Applicants will provide such material in the form of a declaration if so desired.

For all of the reasons described above, the art rejections are improper and must be withdrawn, specifically as the references cited are unavailable and/or fail to teach or suggest the present invention. Consequently, reconsideration and withdrawal of the rejections under 35 U.S.C. §§ 102 and 103 are respectfully requested.

### **REQUEST FOR INTERVIEW**

If any issue remains as an impediment to allowance, prior to issuance of any paper other than a Notice of Allowance, a further interview, is respectfully requested, with the Examiner and his supervisor, and, the Examiner is respectfully requested to contact the undersigned to arrange a mutually convenient time and manner for such an interview.

### **CONCLUSION**

In view of the remarks made herewith, the application is in condition for allowance. Favorable reconsideration of the application, and prompt issuance of a Notice of Allowance are earnestly solicited. The undersigned looks forward to hearing favorably from the Examiner at an early date.

Respectfully submitted,  
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